

REMARKS/ARGUMENTS

Reconsideration of this application and entry of the foregoing amendment are respectfully requested.

The specification has been amended to correct the number of the PCT from which this application claims priority.

The Examiner's comments regarding the priority claim are noted. Submitted herewith is a copy of PCT/GB02/02278, as well as certified copies of the two British priority documents. The Examiner is requested to acknowledge receipt of these documents and grant of the priority claims.

Claims 77-79, 84, 89-91, 93 and 95 stand rejected under 35 USC 112, second paragraph, as allegedly being indefinite. Withdrawal of the rejection is submitted to be in order for the reasons that follow.

Respectfully, it is believed that one skilled in the art would find the proviso, which reads 'except for the compounds in which A and B are both either $-N(CH_3)_2$ or $-N(CH_2CH_3)_2$ ', to be clear and would understand that it excludes all the compounds indicated by the Examiner. Specifically, all compounds of Formula (I) in which A and B are as shown below are excluded from the claims:

Compound	A	B
i)	$-\text{N}(\text{CH}_3)_2$	$-\text{N}(\text{CH}_3)_2$
ii)	$-\text{N}(\text{CH}_3)_2$	$-\text{N}(\text{CH}_2\text{CH}_3)_2$
iii)	$-\text{N}(\text{CH}_2\text{CH}_3)_2$	$-\text{N}(\text{CH}_3)_2$
iv)	$-\text{N}(\text{CH}_2\text{CH}_3)_2$	$-\text{N}(\text{CH}_2\text{CH}_3)_2$

As no confusion is believed to result from the language used, no amendment is seen to be necessary and none has been made. The Examiner is requested to reconsider her position and withdraw the rejection.

Claims 79 and 95 stand rejected under 35 USC 102(b) as allegedly being anticipated by Wagner in light of The Merck Index. Withdrawal of the rejection is submitted to be in order for the reasons that follow.

Wagner discloses a method for decontaminating blood and cellular components using certain phenothiazinium dyes and mentions at page 8 of WO 91/16911 methylene blue, toluidine O, thionin, azure A, azure B and azure C. None of the dyes disclosed by Wagner fall within the scope of the present claims. The chemical structures of the dyes disclosed by Wagner (obtained from www.sigma-aldrich.com) are attached. It will be clear that methylene blue is not within the scope of the present claims as it is a compound of Formula (I) in which A = B = $-\text{N}(\text{CH}_3)_2$. The other dyes either have a ring substituent (e.g., toluidine O) or have as at least one of R' or R'' as H and thus fall outside the scope of the present claims.

There is no teaching or suggestion in WO 91/16911 that the method as presently claimed and limited to the sub-group of compounds of Formula (I) (see comments above responsive to the rejection under 35 USC 112, second paragraph) would be useful for sterilizing a surface or

fluid. Furthermore, it could not have been expected that the sub-group of compounds claimed would have advantageous properties (over the closest related dyes, methylene blue and ethylene blue) in the present method.

The advantageous properties are illustrated throughout the specification, for example:

- Para [0183] states that in general examples of the present sub-group 'are all efficient PDT agents ... being much more active than methylene blue or ethylene blue' (i.e. the compound of Formula (I) in which A = B = -N(CH₂CH₃)₂).
- Para [0183] also states that not only the 'increased photoactivity of these compounds, but also their relative lack of dark toxicity compared with methylene blue. This is a considerable advantage in therapeutic terms.'
- Para [0225] of the specification states 'it may be seen that there is a substantial bacterial inactivation with the trend in the group being a decrease from methylene blue to ethylene blue followed by an increase of almost 1000 fold up to the tetra-n-butyl phenothiazinium derivative.'

In view of the above, reconsideration and withdrawal of the rejection are requested.

Claims 77, 79, 89, 90, 93 and 95 stand rejected under 35 USC 102(b) as allegedly being anticipated by Wilson et al in light of The Merck Index. Withdrawal of the rejection is submitted to be in order for the reasons that follow.

Wilson et al discloses a method of disinfecting or sterilizing tissues in the oral cavity or a wound or lesion in the oral cavity. Wilson et al lists a random selection of dyes and other compounds at column 2 and in Table 1. As noted in connection with the above rejection based on Wagner, none of these compounds falls within the present definition of compounds of Formula (I).

There is no teaching or suggestion in USP 5,611,793 that the method as presently claimed and limited to the sub-group of compounds of Formula would be useful for treating microbial infections, etc., or sterilizing a surface or fluid. Furthermore, as discussed above in connection with Wagner, from data presented in the specification it will be clear that it could not have been expected that the sub-group of compounds claimed would have advantageous properties (over the closest related dyes, methylene blue and ethylene blue) in the method.

In view of the above, reconsideration is requested.

Claims 79, 84 and 95 stand rejected under 35 USC 103 as allegedly being obvious over Wagner in light of The Merck Index and in view of Shanbrom. Withdrawal of the rejection is submitted to be in order for the reasons that follow.

The Examiner indicates that the difference between Wagner and the presently claimed subject matter is that Wagner fails to teach the administration of the phenothiazinium dye in a conjugate or composite formulation with a polymer. The Examiner relies on Shanbrom as teaching the organic polymer material to which a disinfectant dye is adsorbed.

Basis for the Examiner's inclusion of claims 79 and 95 in this rejection is not understood as claims 79 and 95 do not relate to conjugates or composites, or to adsorption of dyes onto polymers. It is believed that the Examiner may have misinterpreted these claims, specifically the meaning of P (which can be 1, 2 or 3) in the structure of Formula (I). It is respectfully pointed out that, if the Examiner is of the view that when P is 2 or 3 then the structure is that of a conjugate/composite/polymeric, that view is in error. P is simply represented as 1, 2 or 3 to balance the electronic charges of the cation (+ charge on the S atom) and the anion X which has a 1, 2 or 3 negative charge (depending on what the anion is).

With respect to claim 84, both Wagner and Shanbrom disclose methods employing dyes outside the scope of the present claims. Neither patent, taken alone or in combination teaches or would have suggested the use of the present dyes in the present sterilizing method, and neither patent would have suggested or teaches the advantageous properties obtained, as discussed above.

In view of the above, reconsideration is requested.

Claims 77, 79, 89-91, 93 and 95 stand rejected under 35 USC 103 as allegedly being obvious over Wilson in light of The Merck Index and in view of Biel. Withdrawal of the rejection is submitted to be in order for the reasons that follow.

Biel was published on August 30, 2001 which is after Applicants' first priority date. Support for each of claims 77, 78, 89-91, 93 and 95 can be found in GB 0113121.8, thus Biel is not citable as prior art and the rejection is, therefore, moot.

In any event, Biel discloses a random set of dyes, particularly methylene blue which, as discussed above, is excluded from the presently claimed methods.

Both Wilson and Biel disclose methods employing dyes outside the scope of the present claims and neither patent, taken alone or in combination, teaches or would have suggested the use of the present dyes in the present sterilizing method. Further, neither patent teaches or would have suggested the advantageous properties obtained as discussed above.

In view of the above, reconsideration is requested.

Claims 77 and 93 stand rejected under 35 USC 103 as allegedly being obvious over Biel in view of The Merck Index and Wainwright et al. Withdrawal of the rejection is submitted to be in order for the reasons that follow.

As discussed above, Biel is not citable as prior art and thus the rejection is moot.

In any event, both Biel and Wainwright disclose methods employing dyes outside the scope of the present claims. Neither patent, taken alone or in combination, teaches or would have suggested the use of the present dyes in the present sterilizing method. Further, neither patent teaches or would have suggested the advantageous properties obtained, as discussed above. Accordingly, reconsideration is requested.

This application is submitted to be in condition for allowance and a Notice to that effect is requested.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: Mary J. Wilson
Mary J. Wilson
Reg. No. 32,955

MJW:tat
901 North Glebe Road, 11th Floor
Arlington, VA 22203-1808
Telephone: (703) 816-4000
Facsimile: (703) 816-4100